SUMMARY OF THE QUALITY SYSTEMS COMMITTEE TELECONFERENCE JANUARY 7, 2000

The Quality Systems (QS) Committee of the National Environmental Laboratory Accreditation Conference (NELAC) met by teleconference on January 7, 2000, at 1 p.m. Eastern Standard Time (EST). The meeting was led by its chair, Mr. Joe Slayton of the U.S. Environmental Protection Agency (USEPA) Region III. A list of action items is given in Attachment A. A list of participants is given in Attachment B. The list of parking lot issues includes items from the Fifth NELAC Annual Meeting (NELAC V) and the Fifth NELAC Interim Meeting (NELAC Vi) (Attachment C). Attachment D describes the QS Committee's guiding principles for reviewing comments and the NELAC Standard. Attachment E presents the QS Committee approach to handling comments and the commenter template. Attachment F is the updated table that logs and documents the status of comments received by the QS Committee. The QS committee's resolution of comments in items #13 and #14 listed in the log and status table (Attachment F) are documented in Attachments G and H, respectively. *The purpose of the meeting was to discuss the resolution of comments received by the QS Committee.*

TELECONFERENCE ATTENDANCE

The attendance at this meeting and at some previous meetings was low. Committee members are encouraged to participate in all meetings (see List of Participants, Attachment B).

ACTION ITEMS

Several action items were discussed during the meeting and are summarized in Attachment A. The action items that were discussed include: update the "homework table" to include comments received from the NELAC Vi meeting, send homework to QS committee members; inform Lisa Doucet of the times and dates of the meetings; determine if QS committee's "guiding principles" can be a fixed, stand-alone document on the NELAC Website as opposed to an attachment to the minutes; and forward comments to other committees as appropriate.

Homework

This meeting focused on addressing the remaining comments that had been submitted since the NELAC V meeting. The comments that were discussed were items #8, #10, #13, and #14. The comments and responses for #13 and #14 are included in Attachments G and H, respectively.

Item #8 from Lehigh County Authority

The committee considered this comment and agreed to forward the original comment and the committee's response to Chapter 4.

Item #10 from Catalyst

The two comments submitted addressed process issues. The first comment suggested posting the QS guiding principles and suggestions for providing comments on the NELAC Website as separate documents and not as attachments to meeting minutes. The committee is seeking input from the NELAC Board of Directors with regard to placing the guiding principles on the NELAC Website as a stand-alone document. Also, the board will be posting instructions for submitting comments on the NELAC Website. The second comment addressed the table format for submitting comments to the committee. The table format has already been changed (See Attachment E).

Item #13 from Kodak

The comments and committee responses are included in Attachment G. Attachment G includes revisions made following the 1/7/00 meeting to reflect committee discussion. In addition, highlights of the committee discussion and the rationale are described below.

Appendix D1.1.a.1

The committee agreed with comment 1. However, they did not agree to changes for comments 2, 3, and 4. Therefore, the proposed change was not accepted. In order to address comment #1, the committee agreed to delete "acceptance" and insert "the" for the following change:... to assess the batch.

Appendix D, Second Introductory paragraph

The committee agreed that a customer's data quality objectives (DQOs) may be tighter than the laboratory's established criteria. However, the standard only requires a laboratory to have the procedures. The standard, as written, gives flexibility to allow for more stringent DQOs. Therefore, the committee is not proposing a change in response to this comment.

Section 5.1 b) second paragraph; 5.9.4.2; 5.13.a

The committee understood this comment to suggest that the standards consider the quality control requirements for a test method first, followed by what quality control a customer needs; with no NELAC minimum for quality control. The committee cannot agree with such a fundamental change as their function is to establish an essential minimum level of quality control.

QS chapter and appendices (all), Section 5.1

The committee agrees that terms in the QS Standard and its appendices may have different meanings in various USEPA programs. This comment involves terms and definitions and was sent to the Chapter 1 committee.

Appendix D, Section D.1.1.b.1 and D.1.1.b.2

The committee understood this comment to suggest that test method language should take precedence over NELAC Standard language. In addition, the committee considered the comment to be broader than the proposed change. The committee will consider this comment in a detailed discussion about matrix spikes and laboratory control samples. This comment has been added to the Parking Lot (See Attachment C).

Section 5.9.4.2.2b

The committee considered the example in this comment to be an excellent one. However, the benefit of standard criteria outweighs this example. The committee is committed to calibration verification at the beginning and end of a batch, however, the committee will consider varying the concentration. The committee will seek out the opinion of metal experts on this issue.

Item #14 Test America

The comments and committee responses are included in Attachment H. Attachment H includes revisions made following this meeting, which reflect the committee discussion. The meeting concluded during the discussion on section 5.12.3.3 and the need to clarify "time of analysis." This will be the starting point for discussion at the next meeting.

QS TELECONFERENCE SCHEDULE

In order to address comments more quickly the committee has agreed to meet twice a month and the next three meeting dates are shown below. March meetings will be scheduled at a later date.

Monday, January 24th	2-4 p.m. (EST)
Wednesday, February 9th	1-3 p.m. (EST)
Wednesday, February 23rd	1-3 p.m. (EST)

Attachment A

ACTION ITEMS
QUALITY SYSTEMS COMMITTEE
JANUARY 7, 2000

Item No.	Action Item	Date to be Completed
1.	Mr. Slayton will submit the dates and times of the next QS meetings to Lisa Doucet via e-mail.	January 14, 2000
2.	Mr. Slayton will update the comment “homework” table to include the six comments received from the interim meeting.	January 14, 2000
3.	Mr. Slayton will send the homework (i.e., the new comments) to committee members.	January 14, 2000
4.	Mr. Slayton will send comment #8 from the Lehigh County Authority and the committee’s response to Chapter 4.	January 14, 2000
5.	Mr. Slayton will request input from Jeanne Hankins whether the QS committee's "guiding principles" can be a fixed, stand-alone document on the web site instead of attached to QS minutes.	January 14, 2000
6.	Mr. Slayton will send the comment from Kodak (#13) concerning terms and definitions to Chapter 1.	January 14, 2000

Attachment B

PARTICIPANTS
Quality Systems Committee
January 7, 2000

Name	Affiliation	Phone Numbers
Mr. Joe Slayton	USEPA, Region III, OASQA	T: 410-305-2653 F: 410-305-2698 E: slayton.joe@epamail.epa.gov
Ms. Mary K. Bruch (Absent)	Mary Bruch Micro Reg. Inc.	T: 540-338-2219 F: 540-338-6785 E: mkesterm@aol.com
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Mr. David Mendenhall (Absent)	Utah Department of Health	T: 801-584-8470 F: 801-584-8501 E: dmendenh@doh.state.ut.us
Mr. Jeff Nielsen	City of Tallahassee Water Quality Division	T: 850-891-1232 F: 850-891-1062 E: nielsenj@mail.ci.tlh.fl.us
Mr. Scott D. Siders	Illinois Environmental Protection Agency	T: 217-785-5163 F: 217-524-0944 E: epa6113@epa.state.il.us
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Attachment C

PARKING LOT ITEMS/ISSUES
Quality Systems Committee

Items/issues will remain in the Parking Lot until they are completed. Items three and four were added to the parking lot following the January 7, 2000 meeting.

1. Review terms in Chapter 5 for terms needing clarification, e.g., "such as," "independent standard," "alternate source," "second" or "alternate source."

2. Combine "Analyst Training" and "Verification" into same section.

3. Standard and Comments on Appendix D, Section D.1.1.b1 & D.1.1.b2 (NELAC July 1999) (See Attachment G.**)**

Current Standard:
Laboratory Control Sample (LCS) - (QC Check Samples) Shall be analyzed at a minimum of 1 per batch of 20 or less samples per matrix per sample extraction or preparation method... ...NOTE: the matrix spike (see 2 below) may be used in place of e of this control as long as the acceptance criteria are as stringent as for the LCS.

Comments submitted by Kodak:
1) It is not clear from the wording in these two paragraphs which frequency would take precedence when matrix spikes are used instead of LCS, LCS, which includes the batch criterion, or MS, which does not include a batch specification.

2) If the wording I proposed in Section 5.1.b were to be approved, the USEPA Program objectives, as laid down in the approved method, would take precedence over the requirement in paragraph D.1.1.b)1). I think this is appropriate; USEPA and NELAC must maintain a sensitivity to the balance between mandating quality control requirements and the cost to the regulated community to perform the analysis.

EXAMPLE: Method 625 requires QC Check Samples to be run only if the Matrix Spike analysis fails to meet acceptance criteria. Matrix Spikes are specified at a 5% frequency, same as Section D.1.1.b)2). In the case of my laboratory and my company's permitted discharge, we are required to take 1 sample for Method 625 analysis on an 8-day cycle. We also take an influent sample to our treatment plant, so we actually have 2 samples per 8-day cycle. We use a turnaround time of 7 days (customer requirement). We therefore 'batch' the preparation of the two samples one day per week. If we were required to prepare an LCS for each 'batch', our sample load for the test would increase by approximately 40% (considering the monthly/every 20 matrix spike), as would the discharge of extraction solvents (methylene chloride - a presumed carcinogen) to the atmosphere. Note: We make a point of analyzing a spiked blank as an LCS along with our matrix spikes to assure that there is always a QC Check Sample available for evaluation in the event of a Matrix Spike failure.

3) It should be made clear that the LCS , when used for batch acceptance, is tied to the sample preparation batch, not necessarily the instrument analytical batch. It is very common (in metals analysis, for example) to have multiple days' digestions queued to run on an ICP in the same analytical batch. The LCS should only be evaluated against the samples with which it was prepared.

Note that for some methods such as Method 624, there is not a distinction between preparation and analytical batches, because the preparation is part of the instrument analytical process.

Comment 4) I would assume, but it is not stated, that the LCS must have all analytes present for a multi-analyte method such as ICP or 625. In this case, the allowance for using the matrix spike results would seem to introduce a potential inconsistency for those methods which specifically allow or state a subset of analytes for matrix spikes. In any event, the LCS in a method such as 625 is critical for evaluating the performance of the analytical system in the event of matrix spike failure (as required in the method). I therefore don't think this exception (matrix spike substituted for LCS) is appropriate.

Comment 5) Since the LCS is a quality control sample used primarily for assessing the preparation of a sample batch, allowance/consideration should be made for methods which have built-in verification of the quality of the sample preparation - i.e. surrogates.

4. Standard and Comments on Section #: 5.9.4.2.2 b (NELAC July 1999). (See Attachment G.)

Current Standard:
b*) A continuing instrument calibration verification must be repeated at the beginning and end of each analytical batch. The concentrations of the calibration verification shall be varied within the established calibration range...*

Comments submitted by Kodak:
Please refer to my comments and recommended change for Section 5.1b). A case in point: Method 200.7 has specific requirements (varying by the published version) for the concentrations to be used in the LPC/IPC solution, which is, in my interpretation, a CCV. This solution is required to be analyzed after every 10 samples and at the end of the batch. One could argue that the requirement in this section of the standard to vary the concentration of the CCV is "more stringent" than that of 200.7. To be compliant with program requirements, the specific version of Method 200.7 must be followed. What value would be added to the quality of data by requiring at least one (and presumably two, if the concentrations are to be truly varied) more CCV at the beginning or end of the run to satisfy the requirements of this section?

Note also that Standard Methods, which is used as an authoritative source for many State programs, specifies in Section 3020 of the 18th edition that a midpoint standard be run for the CCV. One (hopefully temporary) effect of requiring varying concentrations for the CCV is that NELAP-approved laboratories that must also adhere to non-NELAC State programs will be required to run both midpoint and varying concentrations of CCVs.

EXAMPLE: We were running an analysis for Silver by Method 272.1, and running a CCV of 1mg/L, with a calibration range up to 4 mg/L. We were told by a state auditor that we must change the CCV concentration to 2 mg/L, even though we had chosen the 1 mg/L standard because it is a typical action level for our customers. Requiring that the CCV be varied in concentration would not really add value to the analysis for these customers, and requiring a midpoint standard actually decreases the value when considered against their action limits.

GUIDING PRINCIPLES/REVIEW CRITERIA **Attachment D**

The QS Committee established a set of criteria by which to evaluate the requirements specified in Chapter 5. The standards in Chapter 5 should meet the criteria listed below:

Flexible:

Allow laboratories freedom to use their experience and expertise in performing their work and allow for new and novel analytical methods and approaches, (e.g., Performance Based Measurement System [PBMS]). That the standards specify the "What" and avoid were possible the "How To", (e.g., control limits must be developed to determine if a QC check result is acceptable, the standards do not specify how the laboratory is to determine these limits).

Auditable:

Sufficient detail is included so that the accrediting authorities evaluate laboratories consistently and uniformly.

Practical/Essential:

The standards are necessary QA policies and QC procedures and that these standards should not place an unreasonable burden upon laboratories.

Widely Applicable:

International scope- consistent with ISO Guide 25. Represent QA policies, which establish essential QC procedures, that are applicable to environmental laboratories regardless of size and complexity.

Appropriate For The Use of the Data:

Helps ensure that associated environmental data is of known quality and that the quality is adequate for the intended use of the data.

Attachment E

REVIEW GUIDELINES, and
COMMENTER TEMPLATE
Quality Systems Committee
January 7, 2000

QS Approach: Comments Received and QS Response:

1. A form letter will be sent to each commentor notifying them of receipt of the comment and of the QS's approach to reviewing comments and associated updates to the standards.

2. QS will consider the comments in the order received.

3. A QS committee member will be designated as the lead on each set (or up-set) of the comments from each commentor, who will provide written comments and who will lead a discussion with the full committee on any proposed changes to the standards (including providing the proposed standard language).

4. Proposed changes to the standards will be captured in the QS meeting minutes which are posted on the NELAC Web page.

5. All comments and written responses will be attached to QS meeting minutes.

6. No colors to be used in the comments nor in the response. Use double underlines for additions and strike-outs for removal of items.

7. All comments are to be provided in WordPerfect or rich text format using the following the following topic listing:

Comment ID #: **Date:**

Commenter's Name:
Affiliation:

Email Address:

Committee Lead on Response (Name):
::
::::::

Comment #1: Standard Rev. # , SECTION#

TO BE COMPLETED BY THE COMMENTER:

A: Current Standard Text

B: COMMENT with Rationale

C: Proposed Wording Change

TO BE COMPLETED BY THE COMMITTEE:

D: OUTCOME (Including any proposed change)

E: RATIONALE

Comment #2: Standard Rev. #, SECTION#

TO BE COMPLETED BY THE COMMENTER:

A: Current Standard Text

B: COMMENT with Rationale

C: Proposed Wording Change

TO BE COMPLETED BY THE COMMITTEE:

D: OUTCOME (Including any proposed change)

E: RATIONALE

Attachment F - Comments to QS Committee
Log & Status Table 12/7/99

From (Organization)	From (Person)	Date Received	Commentor Notified of Receipt (Y/N)	Format OK? (Y/N) & WORDPERFECT OR WORD OR RICH TEXT	Number Assigned	[redacted]	Due Date	Compl. Date
15 Wi DNR	A. Sotomayor	4/1/99	Y	Y	wisc_1 **One**		~~6/2~~ **9/22/99**	10/18/99
16 Navy	Elsie Munsell	4/1/99	Y	Y	Navy_1.wpd **Two**		6/2 **9/22/99** **9/22/99**	6/17/99
17 Arizona	George Avery	4/29/99	Y	N	not electronic **Three**		~~5/26~~ **9/22/99**	9/22/99 12/7/99
South Carolina	Carol Smith	6/24/99	N	N (hardcopy)	**Four**		**10/15/99**	11/26.99 12/7/99
Fl Dept. of Health	Steve Arms	7/14/99	Y	Y(File not avail)	**Five**		**10/15/99**	10/15/99
Hillsboroght Co. Water Dept.	Steve Axelrod	8/10/99	Y	N(File not avail)	**Six**		**10/15/99**	10/15/99
DOD	Jackie Sample	8/24/99	Y	N (Yes Email)	**Seven**		**10/15/99**	11/16/99
Lehigh Co. Authority	Donna Farber	9/2/99	Y	N (Yes Email)	**Eight**		**10/15/99**	
W. Coast Analytical Service, Inc.	Jack Northington	9/1/99	Y	N (Yes Email)	**Nine**		**10/15/99**	12/7/99
Catalyst	Jerry Parr	9/7/99	Y	N (Yes Email) Gen. Questions	**Ten**		**10/15/99**	
New Hampshire	Charles Dyer	?	N	Y(file not avail)	**Eleven**		**!0/1/99**	10/15/99
CA ELAB	Steve Boggs	9/22/99	Y	Y	**Twelve**		**10/15/99**	12/7/99
Eastman Kodak	Don Zahniser	9/22/99	Y	Y	**Thirteen**		**10/15/99**	
Test America	Paul Juno	9/22/99	Y	Y	**Fourteen**		**10/15/99**	
WI DNR	A. Sotomayor	9/25/99	Y	Y	**Fifteen**		**10/15/99**	12/7/99

Note: The comments will be discussed during QS Committee meetings and the completed forms will be attached to the minutes. The final version of the tables/sections of tables will be forwarded by the lead after the committee meeting so that it can be attached to the minutes. As the final response will be the consensus of the QS committee the name of the group leader/s will not be included in the minutes/web posting.

Comment #13, Eastman Kodak Company **Attachment G**

Comment ID #: DZ-1 , Source of Comments: D. Zahniser QS Lead on Response (Name):

Standard Rev. # July 1999 Appendix D1.1 a) 1)	COMMENT	QS Leader Provided Proposed Change (Commentor Leave Blank)	RATIONAL (from QS Leader) (Commentor Leave Blank)
...The results of this analysis shall be one of the QC measures to be used to assess batch acceptance. The source of contamination must be investigated and measures taken to correct, minimize, or eliminate the problem if *I) the blank contamination exceeds a concentration greater than 1/10 of the measured concentration of any sample in the associated sample batch and* *ii) The blank contamination exceeds the concentration present in the sample and is greater than 1/10 of the specified regulatory limit* *Any sample associated with the contaminated blank shall be reprocessed for analysis or the results reported with appropriate data qualifiers.*	I fear that this section tries to compress too many issues into a small space. Comment 1 - The statement of using blank criteria for batch acceptance is inconsistent with the qualification of results. Comment 2 - While in some cases a batch should be rejected due to blank contamination, in others (e.g. high sample concentrations or samples for which the analyte is not detected) there may be data that is usable and defensible despite the blank concentration. Comment 3 - The standard as written does not allow for blank contamination that is below the detection limit. This may be implicitly assumed, but it is not explicitly stated. As such, when the amount of contamination in the blank is not detected, it is not possible to demonstrate that the level of contamination is less than 1/10 of sample or regulatory limit concentrations that are less than 10 times the detection limit. Comment 4 - Some regulatory limits are less than 10 times the detection limit for available methods used to monitor against the regulatory limits; any detected blank concentration would therefore be cause for rejection of data.	Comment 1 - Delete “acceptance” and insert “the” for the following change: ... to assess the batch. No other changes.	

	Proposed Change *...The results of this analysis shall be one of the QC measures to be used to assess data quality. If the analyte is found in the blank at a concentration above the detection limit, the source of contamination must be investigated and measures taken to correct, minimize, or eliminate the problem.* *With the following allowed exceptions, any sample associated with a blank showing a detected quantity of analyte shall be reprocessed for analysis, or the reported results of the sample analysis must be accompanied by appropriate data qualifying statements or codes.* *I) Samples with measured concentrations in excess of 10 times the measured concentration of the blank may be reported without qualification for blank contamination.* *ii) Samples that measure below the detection limit for the method may be reported as not detected without qualification for blank contamination.*		

Comment ID #: DZ-2 , Source of Comments: D. Zahniser QS Lead on Response (Name):

July 1999 **Appendix D, Second Introductory Paragraph** *The laboratory shall have procedures for the development of acceptance/rejection criteria where no method or regulatory criteria exist.*	**Comment** A customer's data quality objectives may be tighter than the laboratory's established criteria. **Recommended Change:** *The laboratory shall have procedures for the development of acceptance/rejection criteria where no method or regulatory criteria exist, and shall adjust acceptance criteria if necessary to meet the data quality objectives for the samples being analyzed.*	No change.	

Comment ID #: DZ-3 , Source of Comments: D. Zahniser QS Lead on Response (Name):

July 1999 **5.1 b), second paragraph** *If more stringent standards or requirements are included in a mandated test method or by regulation, the laboratory shall demonstrate that such requirements are met. If it is not clear which requirements are more stringent, the standard from the method or regulation is to be followed.* ***5.9.4.2*** *...If more stringent standards or requirements ar included in a mandated test method or regulation, the laboratory shall demonstrate that such requirements are met. If it is not apparent which standard is more stringent, then the requirements of the regulation or mandated test method are to be followed.* ***5.13.a)*** *8) identification of the test method used, or unambiguous description of any non-standard method used;*	Comment - I am concerned that the existing wording in Sections 5.1 and 5.9 leaves too much room for interpretation. In addition, I am concerned that in some cases NELAC may be requiring quality control that is above and beyond existing EPA methods that already have robust quality control, or that may not be warranted by customers' data quality objectives, thereby increasing environmental monitoring costs without producing a corresponding improvement in the quality of data required. I perceive that the decision tree should look to the EPA-approved methods first for quality control requirements and acceptance criteria, then to the NELAC standards for specifying quality control that is not addressed in the approved method, or for which the approved method does not specify acceptance criteria (or how they are determined). I have a third concern, which relates to PBMS. From statements I have heard in past NELAC and other professional meetings, there seems to be a prevailing opinion that because SW846 has been defined by EPA to be a guidance document, laboratories are automatically empowered to make changes not only to the procedural steps of the SW846 methods, but to the acceptance criteria as well. In my opinion, if a customer specifies an analytical procedure (e.g. - 8270) by which results are to be obtained, that is a defacto statement of data quality requirements. In such a case, the laboratory is not only obligated to meet the acceptance criteria in the method, but to describe what deviations, if any, it has made from the cited procedure in the analytical report. While there may be another place in the standard to express my concerns, section 5.1 closely follows the PBMS statement and deals with a similar issue, and Section 5.13.a) is the place to address communication of procedural variations to the customer.	No Change.	

Proposed Changes:

First, a new definition for the glossary:

Reference Method: *A citation of a procedure for analysis of environmental samples from Federal or State regulations, National standards, guidance documents or other published literature that is generally accepted as authoritative by the environmental regulatory community. Any Reference Method citation must satisfy applicable USEPA and/or State program requirements, and customer data quality objectives for the samples being analyzed.*

Recommended replacement for the language in the standard, Section 5.1:

A laboratory shall adhere to quality assurance and quality control requirements of Reference Methods cited by applicable regulations, its customers, or documentation within the laboratory's quality system. Procedural departures (if permitted) may not degrade the acceptance criteria specified in a Reference Method unless agreement from the customer for alternate acceptance criteria is obtained in writing prior to analysis of samples.

If this standard specifies quality assurance and/or quality control requirements that do not exist in the Reference Method, then the requirements of this standard shall be <u>added</u> to those of the Reference Method.

Second recommended change: Delete the cited text in 5.9.4.2, since it is addressed in the proposed language for Section 5.1.b).

Third recommended change to Section 5.13.a)

8) identification of the test method used, procedural variations from any cited Reference Method, or unambiguous description of any non-standard method used;

Comment ID #: DZ-4 , Source of Comments: D. Zahniser		QS Lead on Response (Name):	
July 1999 **Quality System chapter and appendices (all), Section 5.1**	**Comment** There are terms used in the Quality Systems standard and its appendices that may or may not have the same meaning in the various EPA programs.	Agree. Should bring to attention of Chapter 1 Committee	
	Proposed Change That the Quality Systems committee identify terms that are identified in the glossary by a specific format (e.g. boldface, italics) wherever they are used, and add the following (or similar) to Section 5.1: *d) This Standard uses terms that are intended to have specific definitions as laid out in the NELAC Glossary. These terms are identified in print with a **boldface/italic** style to avoid ambiguity that may arise if is used in a different manner in other environmental literature.*		

Comment ID #: DZ-5 , Source of Comments: D. Zahniser QS Lead on Response (Name):

July 1999	Comments		
Appendix D, Section D.1.1.b)1) & D.1.1.b)2) 1) *Laboratory Control Sample (LCS) - (QC Check Samples) Shall be analyzed at a minimum of 1 per batch of 20 or less samples per matrix per sample extraction or preparation method... ...NOTE: the matrix spike (see 2 below) may be used in place of e of this control as long as the acceptance criteria are as stringent as for the LCS.*	1) It is not clear from the wording in these two paragraphs which frequency would take precedence when matrix spikes are used instead of LCS, LCS, which includes the batch criterion, or MS, which does not include a batch specification. 2) If the wording I proposed in Section 5.1.b were to be approved, the USEPA Program objectives, as laid down in the approved method, would take precedence over the requirement in paragraph D.1.1.b)1). I think this is appropriate; USEPA and NELAC must maintain a sensitivity to the balance between mandating quality control requirements and the cost to the regulated community to perform the analysis. EXAMPLE: Method 625 requires QC Check Samples to be run only if the Matrix Spike analysis fails to meet acceptance criteria. Matrix Spikes are specified at a 5% frequency, same as Section D.1.1.b)2). In the case of my laboratory and my company's permitted discharge, we are required to take 1 sample for Method 625 analysis on an 8-day cycle. We also take an influent sample to our treatment plant, so we actually have 2 samples per 8-day cycle. We use a turnaround time of 7 days (customer requirement). We therefore 'batch' the preparation of the two samples one day per week. If we were required to prepare an LCS for each 'batch', our sample load for the test would increase by approximately 40% (considering the monthly/every 20 matrix spike), as would the discharge of extraction solvents (methylene chloride - a presumed carcinogen) to the atmosphere. Note: We make a point of analyzing a spiked blank as an LCS along with our matrix spikes to assure that there is always a QC Check Sample available for evaluation in the event of a Matrix Spike failure. 3) It should be made clear that the LCS , when used for batch acceptance, is tied to the sample preparation batch, not necessarily the instrument analytical batch. It is very common (in metals analysis, for example) to have multiple days' digestions queued to run on an ICP in the same analytical batch. The LCS should only be evaluated against the samples with which it was prepared. Note that for some methods such as Method 624, there is not a distinction between preparation and analytical batches, because the preparation is part of the instrument analytical process. Comment 4) I would assume, but it is not stated, that the LCS must have all analytes present for a multi-analyte method such as ICP or 625. In this case, the allowance for using the matrix spike results would seem to introduce a potential inconsistency for those methods which specifically allow or state a subset of analytes for matrix spikes. In any event, the LCS in a method such as 625 is critical for evaluating the performance of the analytical system in the event of matrix spike failure (as required in the method). I therefore don't think this exception (matrix spike substituted for LCS) is appropriate. Comment 5) Since the LCS is a quality control sample used primarily for assessing the preparation of a sample batch, allowance/consideration should be made for methods which have built-in verification of the quality of the sample preparation - i.e. surrogates.	This will be considered in detail by the QS committee in a discussion about matrix spikes and laboratory control samples.	

	Proposed Change: 1) *<u>Laboratory Control Sample</u> (LCS) - (QC Check Samples) Shall be analyzed at a minimum of 1 per batch of 20 or less samples per matrix type per sample extraction or preparation method except for analytes for which spiking solutions are not available such as.... ...All analytes being determined must be included in the LCS. The results of these samples shall be used to determine sample preparation batch acceptance (or instrument batch acceptance for methods in which the preparation step is integrated into the instrument analytical process). NOTE: for methods which include the analysis of surrogates in every sample, the LCS analysis frequency may be adjusted 1 in 20 samples with no batch requirement, and run in the same analytical batch as the matrix spike as a verification of method performance and for evaluation of potential matrix spike failures.*		

Comment ID #: DZ-6 , Source of Comments: D. Zahniser QS Lead on Response (Name):			
July 1999 **Section #: 5.9.4.2.2 b)** *b) A continuing instrument calibration verification must be repeated at the beginning and end of each analytical batch. The concentrations of the calibration verification shall be varied within the established calibration range...*	**Comment:** Please refer to my comments and recommended change for Section 5.1b). A case in point: Method 200.7 has specific requirements (varying by the published version) for the concentrations to be used in the LPC/IPC solution, which is, in my interpretation, a CCV. This solution is required to be analyzed after every 10 samples and at the end of the batch. One could argue that the requirement in this section of the standard to vary the concentration of the CCV is "more stringent" than that of 200.7. To be compliant with program requirements, the specific version of Method 200.7 must be followed. What value would be added to the quality of data by requiring at least one (and presumably two, if the concentrations are to be truly varied) more CCV at the beginning or end of the run to satisfy the requirements of this section? Note also that Standard Methods, which is used as an authoritative source for many State programs, specifies in Section 3020 of the 18th edition that a midpoint standard be run for the CCV. One (hopefully temporary) effect of requiring varying concentrations for the CCV is that NELAP-approved laboratories that must also adhere to non-NELAC State programs will be required to run both midpoint and varying concentrations of CCVs. EXAMPLE: We were running an analysis for Silver by Method 272.1, and running a CCV of 1mg/L, with a calibration range up to 4 mg/L. We were told by a state auditor that we must change the CCV concentration to 2 mg/L, even though we had chosen the 1 mg/L standard because it is a typical action level for our customers. Requiring that the CCV be varied in concentration would not really add value to the analysis for these customers, and requiring a midpoint standard actually decreases the value when considered against their action limits. **Proposed Change** Remove the text that requires varying the concentration	No Change.	

Comment #14, Test America **Attachment H**

Comment ID #: , Source of Comments (Name): Paul Junio, TestAmerica QS Lead on Response (Name):

Standard Rev. # SECTION# and QS Standard Narrative (To Filled In by Commentor)	COMMENT with Rationale to QS (To Be Filled in by Commentor) New Wording for Standard (To Be Filled In by Commentor)	QS Leader Provided Proposed Change (Commentor Leave Blank)	RATIONALE (from QS Leader) (Commentor Leave Blank)
EDITORIAL CHANGES			
5.11.2 f) Procedures to be used when samples which show signs of damage or contamination.	Delete unnecessary "which" 5.11.2 f) Procedures to be used when samples ~~which~~ show signs of damage or contamination.	OK, but no action necessary	Change already included in the Nov 10, 1999 draft.
5.12.1 d) … The reason for the signature or initials shall be clearly indicated in the records such as "sampled by", "prepared by", or "reviewed by").	Delete unnecessary ")" 5.12.1 d) … The reason for the signature or initials shall be clearly indicated in the records such as "sampled by", "prepared by", or "reviewed by"~~)~~.	Delete dangling parenthesis at end of sentence.	Editorial correction
5.11.3a 1) All samples which require thermal preservation shall be considered acceptable if the arrival temperature is either within +/-2°C of the required temperature or method specified range.	Delete redundant "+/-" 5.11.3a 1) All samples which require thermal preservation shall be considered acceptable if the arrival temperature is either within ~~+/-~~2°C of the required temperature or method specified range.	Delete the +/- just prior to the 2°C in the sentence.	Editorial correction

Comment ID #: , Source of Comments (Name): Paul Junio, TestAmerica **QS Lead on Response (Name):**			
Standard Rev. # SECTION# and QS Standard Narrative (To Filled In by Commentor)	**COMMENT with Rationale to QS (To Be Filled in by Commentor)** **New Wording for Standard (To Be Filled In by Commentor)**	**QS Leader Provided Proposed Change (Commentor Leave Blank)**	**RATIONALE (from QS Leader) (Commentor Leave Blank)**
5.9.4.2.1 f) …The lowest calibration standard must be above the detection limit.	I was involved in the debate about this statement at NELAC V, and will attempt to clarify my problems with it. There were 2 separate issues involving quantitation limits and quantitation levels. The lines between the two were crossed during the debate. As it relates to this point, I feel that this sentence should be dropped from the Standard. A calibration standard must be above the detection limit, or the instrument should not see it. If it is visible to the instrument, then the detection limit is incorrect (unreasonably high). If it is not visible to the instrument, then it shouldn't be included in a calibration curve since it has no response. f) Results of samples not bracketed by initial instrument calibration standards (within calibration range) must be reported as having less certainty, e.g., defined qualifiers or flags or explained in the case narrative. ~~must be above the detection limit.~~	No change.	The committee decided that a reference to D.1.4.2.1f will clarify the meaning.

5.10.2.1 f) When a work cell(s) is employed, and the members of the cell change, the new employee(s) must work with experienced analyst(s) in the speciality area and this new work cell must demonstrate acceptable performance through acceptable continuing performance checks (appropriate sections of Appendix D, such as laboratory control samples)... In addition, if the entire work cell is changed/replaced, the work cell must repeat the demonstration of capability (Appendix C).	"Speciality (sic) area" is undefined. This should be a work cell. Also, if the entire work cell is changed/replaced, it can't repeat the demonstration, since it has never performed one in the first place. 5.10.2.1 f) When a work cell(s) is employed, and the members of the cell change, the new employee(s) must work with experienced analyst(s) in the ~~speciality area~~ work cell and this new work cell must demonstrate acceptable performance through acceptable continuing performance checks (appropriate sections of Appendix D, such as laboratory control samples)... In addition, if the entire work cell is changed/replaced, the work cell must ~~repeat~~ perform the demonstration of capability (Appendix C).	5.10.2.1 f) When a work cell(s) is employed, and the members of the cell change, the new employee(s) must work with experienced analyst(s) in that area of the work cell where they will be employed. This ~~the speciality area and this~~ new work cell must demonstrate acceptable performance through acceptable continuing performance checks (appropriate sections of Appendix D, such as laboratory control samples)... In addition, if the entire work cell is changed/replaced, the work cell must ~~repeat~~ perform the demonstration of capability (Appendix C).	Revise statement as suggested. It improves the clarity of the language.

5.11.3a 1) … Samples that are hand delivered to the laboratory immediately after collection may not meet this criteria. In these cases, the samples shall be considered acceptable if there is evidence that the chilling process has begun such as arrival on ice.	The interpretation of "delivered to the laboratory immediately" causes me some concern. It is not uncommon for a client to drive 3 hours to the lab to drop off a sample that was just collected. 5.11.3 1) … Samples that are hand delivered to the laboratory ~~immediately~~ within 3 hours after collection of the last sample may not meet this ~~criteria~~ criterion.	No Change	The current standard language would accommodate a client driving three hours to drop off samples, as long is it there is evidence that the cooling process was started (as already specified in standard). The committee should refrain from adding an arbitrary 3hr time limit on sample receipt, someone will surly want it stretched to 4hrs. Also the argument that that 3 hr time should start after the last sample is collected opens a loop hole: "how long since the first samples was collected?"
5.11.3 c) …If the sample does not meet the sample receipt acceptance criteria listed in 5.11.3.a, 5.11.3.b or 5.11.3.c, the laboratory shall either: a) Retain correspondence and/or records of conversations concerning the final disposition of rejected samples; or...	Section 5.11.3 c) refers to itself. The sample acceptance criteria are actually in 5.11.3 a & c (b is a lab requirement, not an acceptance criterion). The present 5.11.3 c) should be split into parts c) & d). Additionally, subpart a) of 5.11.3 c) should be re-numbered to subpart 1).	5.11.3 c) Where there is any doubt ... The laboratory shall establish whether the sample has received all necessary preparation, or whether the client requires preparation to be undertaken or arranged by the laboratory. 5.11.3 d) If the sample does not meet the sample receipt acceptance criteria listed in ~~5.11.3.a, 5.11.3.b or 5.11.3.c~~ this standard, the laboratory shall either: ~~a~~1) Retain correspondence and/or records of conversations concerning the final disposition of rejected samples; or…	Splitting 5.11.3 c into another section (5.11.3. d) clarifies the language of the standard. Information on sample receipt acceptance criteria exists in other sections besides 5.11.3, for example section D.2.8n.

	5.11.3 c) Where there is any doubt ... The laboratory shall establish whether the sample has received all necessary preparation, or whether the client requires preparation to be undertaken or arranged by the laboratory. d) If the sample does not meet the sample receipt acceptance criteria listed in 5.11.3.a~~, 5.11.3.b~~ or 5.11.3.c, the laboratory shall either: ~~a~~1) Retain correspondence and/or records of conversations concerning the final disposition of rejected samples; or…		
5.12.2 b) All records, including those specified in 5.12.3 and 5.12.4, shall be retained for a minimum of five years from last use	It would be difficult to track the date of "last use" for the purposes of storing records, especially if a record is reviewed some time after a project is completed. This would require a change in the way most labs store data, away from "client specific" records and toward a chronological storage. This adds nothing to data quality, and in fact, makes it more difficult to refer to data. 5.12.2 b) All records, including those specified in 5.12.3 and 5.12.4, shall be retained for a minimum of five years ~~from last use~~ following the generation of the final test certificate.	Changes the sentence to read "shall be retained for a minimum of five years from ~~last use~~ generation of the last data entry in the record.	As discussed at NELCAVi.
5.12.3.3 The essential information to be associated with analysis, such as strip charts, tabular printouts, computer data files, analytical notebooks, and run logs, shall include: a) Laboratory sample ID code; b) Date and time of analysis; ***COMMITTEE MEETING ENDED HERE. DISCUSSION WILL BEGIN HERE AT THE NEXT MEETING.***	Recording the time of analysis is a difficult and burdensome task for any non-automated analysis. Since the Standard only requires reporting the time of analysis for those analyses that have a holding time of 48 hours or less (see Section 5.13.7), and since the time of analysis is not required to be retained for the reconstruction of a continuing instrument calibration (see Section 5.9.4.2.2 c), I propose striking the requirement to note the time of analysis, except in those cases where the holding time is 48 hours or less. 5.12.3.3 b) Date ~~and time~~ of analysis, including the time of analysis for those tests that have a holding time of 48 hours or less;	No change.	The committee agreed that time is critical.

5.13 a) 17) clear identification of numerical results with values outside of quantitation levels	Aside from in the Committee meetings and at the Conference, “quantitation levels” has not been defined. Please clarify its definition in the Standard. 5.13 a) 17) clear identification of numerical results with values outside of quantitation levels (a result above the highest standard or below the lowest standard in the initial calibration).	5.13 a) 17) clear identification of numerical results based on ~~with~~ values ~~outside of quantitation levels~~ above the highest standard or below the lowest standard in the initial calibration).	Unless the committee is willing to address the much needed clarification in definition of quantitation level it should refrain from using those terms in the standard.
D.1.1 b) 1) & 2) Laboratory Control Sample and Matrix Spikes Shall be analyzed at a minimum of 1 per batch of 20 or less samples per matrix type per	This appears to allow for no LCS or MS if there is not an extraction or preparation procedure, i.e., dissolved metals. D.1.1 b) 1) & 2) …per batch of 20 or less samples per matrix type per sample extraction or preparation method or analytical batch except for analytes…	No change	The term batch is inclusive of analytical batch.

(This issue is being raised with the Program Policy and Structure Committee, since that is where the Glossary lies. I am including it here for the sake of discussion.) The second issue regarding quantitation level (or limit) involved its nebulous definition. I am disappointed with the committee’s decision to accept a definition that was still “indefinite”. Since quantitation limits are to be determined on the basis of the intended use of the data, it is possible that in a single batch of analytical data, there could be multiple quantitation limits, depending on the interpretation of “accuracy required by the intended use of the data”. This makes for extremely difficult, if not impossible, reporting of data from many LIMS. The quantitation limit shouldn’t be an “intended use” definition. It should have remained tied to a 40 CFR MDL Study, or should be set as the lowest point in the calibration curve. (That’s where the two issues crossed – a committee member misunderstood this point and thought that I wanted the quantitation limit to be the detection limit.) The definition is also in conflict with Section D.1.4 f) The laboratory must have established procedures to tie detection limits with quantitation limits”. The laboratory can’t have a procedure to tie detection limit to a number that will change on the basis of the intended use of the data (the intended use is out of the laboratory's hands).

I have proposed a new definition for Quantitation Limit, as follows:

Quantitation Limit - the level of the lowest standard in the initial calibration, or 3.3 times the Detection Limit, whichever is higher.

This definition includes aspects of "quantitation level" as envisioned by the QS Committee, and allows for the laboratory to tie quantitation limits to detection limits.

Thank you for taking time to review my comments.